K003272

APR - 4 2001

510(k) SUMMARY

Trade Name: Flo-Boot™ Foot Dorsiflexion Device (Flo-Boot)

Common Name: Flo-Boot

Classification Name: Physical Medicine

Predicate Device: PhleboPump (K952975) manufactured by Prevent Products, Inc., St. Paul, MN.

Description

The Flo-Boot™ Foot Dorsiflexion Device (Flo-Boot) is a pneumatically-operated, foot dorsiflexion device which intermittently rotates the foot about the axis of the ankle joint. It consists of a control module and a disposable boot. The control module contains the pneumatic pump and control electronics. On the exterior of the control module are connections for two boots, a dial for selection of cycles/min, and the on/off switch. The boot is comprised of a fixed baseplate and calf support and a moveable foot plate. An inflatable bladder is placed between the baseplate and the footplate, which upon inflation causes the foot to dorsiflex. This results in a compression of the muscles of the lower extremity, which, in turn causes venous blood to flow, thereby, a) preventing stasis of blood and formation of thrombi in the deep veins of the treated extremity, and b) exercising the ankle joint.

As noted, the device is comprised of two components, a control module and disposable boots. A piston air compressor producing a maximum of 280 mmHg pressure over the 1.5 sec cycle length is connected to a 3-way valve to provide compressed air to the bellows of the 2 boots. A valve controller is used to control the 3-way valve. The exhaust end (Exh) of the valve is open to atmosphere. In the initial position, the valve is OFF. The output will be connected to atmosphere through the exhausting end, and there is no connection between the output and the input. Both the air compressor and the valve controller are controlled by a relay. When the relay is at ON status, the air compressor will run and generate pressure to the valve. The valve controller will turn the valve to ON position. As the valve turns to ON, the compressed air will flow to the valve output. The output connects to a T connector and then to two quick connectors (Q.C., CH 1 and CH2) mounted on the front panel of the system. The CH1 is a normal open (NO) and CH2 is a normal close (NC) quick connector. This design is to prevent damage to the pump is the controller is turned on without connecting any boot to the system. In this configuration, the open CH1 will prevent the buildup of pressure inside the system. When only one boot is used, the boot should connect to CH1 and the CH2 remains closed. When two boots are used, the snap-on connector from the boot will automatically open the CH2 connector. The compressed air will be delivered to the bellows of both boots through lengths of plastic tubing.

To control the timing of both the air compressor and the valve controller, an electronic timing circuit is used. In this circuit, a timebase generator generates an accurate timing

signal with signal period of 10 msec. The signal is sent to a frequency divider to generate the time periods required to control the inflation/deflation rate. In the current design cycle times are 10, 20, and 40 sec and are shown as frequencies of 6, 3, and 1.5 cycles/min on the step switch on the control module. This timing signal is then sent to a monostable flip-flop circuit to generate a 1.5 second control pulse. This control pulse is used to turn on the relay and, therefore, switch on both the air compressor and the valve controller, resulting in inflation of the bellows. When the pulse stops, the air compressor and valve controller turn off and the 3-way valve returns to OFF position. In the OFF position the bellows is open to atmosphere, the bellows deflates, and the footplate will rotate back to the original neutral position.

The boot has 3 components, a single component comprising a fixed baseplate and calf support, a moveable footplate, and an inflatable bellows. Hook-and-loop strips are used to hold the bellows and footplate in place and hook-and-loop straps are used to affix the boot to the wearer. The boot is connected to the control module by a length of plastic hose between CH1 and/or CH1 & CH2 and the respective bellows. The boots are made entirely of plastic materials and no metal connector is used. They are easy to use and disposable.

The Flo-Boot is a non-invasive device that produces dorsiflexion of the foot. In turn, this causes the muscles of the foot and lower extremity to compress the venous plexus therein. The resultant compression causes blood in those veins to move from the extremity towards the heart. Retrograde flow is prevented by unidirectional valves which line the interior of the veins. This mimics the natural pumping mechanisms that occur when the foot undergoes normal dorsiflexion as, for example, in walking. Thus, this device simply activates a normal physiological mechanism and, therefore, is intrinsically safe.

Apart from the intrinsic safety of the device, several other safety features have been designed into the device. Specifically,

1. The inflatable bladder is sized such that it will not over-inflate and cause excessive dorsiflexion.
2. Upon interruption in power the device will default to the unpowered state, which has the bladders open to atmosphere. In the event of a power failure the bladder(s) will deflate and the foot will not remain in the continuous dorsiflexed position.
3. Relevant contraindications will be prominently printed in the Flo-Boot manual and brochures.
4. Warnings will be prominently printed in the Flo-Boot manual and brochures, as well as being displayed on the control module itself. For example, users will be warned to pay special attention to patients with a high risk for decubitis and to use padding or cloth protection between the hook-and-loop straps and the skin. Also, a warning that the device is not explosion proof and should not be used in the presence of flammable anesthetics or gases will be included.
5. The devices manual and brochure will prominently note that this device is only to be used under physician's order.

6. If any component in the circuit controlling the pump were to fail, the pump is immediately inactivated. As a result, no failure can occur in which the pump will

remain in the active pumping state. Thus, the bladder will never over-inflate due to failure of an electronic component.

The Flo-Boot itself is made entirely of plastic and connects to the control module through a plastic tube. Therefore, the user is isolated from all electrical parts. From the point of view of electric safety, this device is a general medical device.

The electrical safety features of the Flo-Boot system were tested using the UL Standards. The major current leakage limits set by the UL standards are shown in Table 1.

Table 1: UL Standards on Major Current Leakage Limits

	Normal Condition	Single Fault Condition
Earth Leakage Current	500	1000
Enclosure Leakage Current	100	500

An Electrical Safety Analyzer (Model 505 Pro, Bio-Tec Instruments, Inc.) was used to test the Flo-Boot control module. This equipment provides all possible single fault conditions, including open ground, open ground and neutral, and open ground and neutral with reversed phase. The test results are listed in Tables 2 and 3. As shown, the electrical safety features of the Flo-Boot system exceed the UL standards.

Table 2: Enclosure Leakage Current

Conditions		Result (μA)	UL Standard (μA)
Single Lead		0.2	<100
	Open ground (gr.)	0.2	<500
	Open gr. & neutral	0.5	
	Open gr. & neutral reverse phase	0.6	
Dual Leads		0.4	<100
	Open gr.	0.4	<500
	Open gr. & neutral	0.4	
	Open gr. & neutral reverse phase	0.4	

Table 3: Ground Leakage Current

Conditions		Result (μA)	UL Standard (μA)
Device Off	Open ground (gr.)	9.2	<500
	Open gr. & neutral	15.9	<1000
	Open gr. & neutral reverse phase	175	<1000
Device On	Open gr.	116.9	<500
	Open gr. & neutral	182	<1000
	Open gr. & neutral reverse phase	188	<1000

Intended Use

This device has several intended uses.

1. The Flo-Boot is intended to intermittently dorsiflex the foot to increase blood flow and prevent deep venous thrombosis (DVT) in patients at risk for that condition.
2. The Flo-Boot is also intended to be used in exercising the ankle joint to restore or maintain range of motion.

Contraindications:

1. The device is contraindicated where pre-existing DVT is diagnosed or presumed.
2. The device is also contraindicated where pre-existing congestive heart failure is diagnosed or presumed.

Summary of Technological Characteristics of the Flo-Boot Compared to the PhleboPump

The Flo-Boot is compared to a predicate device, a foot device called the PhleboPump (K952975), which is manufactured by Prevent Products, Inc., St Paul, MN. The PhleboPump is a Class II device. Table 4 lists the similarities and differences between the Flo-Boot and the PhleboPump. A discussion of the comparison between the devices follows the table.

Table 4: Comparison of Flo-Boot with the Predicate Device (PhleboPump)

Parameter	Flo-Boot	PhleboPump
Indications for use	1. to intermittently dorsiflex the foot to increase blood flow and prevent deep venous thrombosis (DVT) in patients at risk for that condition. 2. to be used in exercising the ankle joint to restore or maintain range of motion.	1. Prophylaxis of Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE) secondary to surgical trauma. 2. Exercise ankle joint
Target population	1. Individuals at risk for development	1. Individuals at risk for development

Parameter	Flo-Boot	PhleboPump
	of DVT 2. Individuals requiring exercising of ankle joint.	of DVT 2. Individuals with or at risk of ankle immobility
Design	1. A control module that cycles a pump to deliver air to inflatable element 2. Upon inflation, the inflatable element causes a footplate to which the user's foot is affixed to rotate about the ankle joint. 3. The rotation about the ankle joint, or dorsiflexion, simulates the walking motion and causes the muscle of the lower leg to stretch and compress the vascular plexus in the lower leg. 4. Compression of the vascular plexus causes blood to move towards the heart and prevents stasis in the lower extremities.	1. A control module to which two foot paddles are attached and to which the user's feet are affixed 2. Upon activation the control module mechanically moves the foot paddles causing the attached foot to rotate about the axis of the ankle joint, thereby producing a dorsiflexion of the foot. 3. Dorsiflexion causes a compression of the vascular plexus in the lower leg. 4. Compression of the vascular plexus causes blood to move towards the heart and prevents stasis in the lower extremities.
Materials	1. The boot is made entirely of biocompatible plastic and hook & loop fasteners. A cotton, non-elastic leg covering will be worn to minimize contact between the boot and the skin. 2. The control module is a metal housing. 3. The control module and the boot are connected by a length of plastic tubing	5. The device is a single unit of mostly plastic. All materials in contact with the user are biocompatible.
Performance	1. Enhances blood flow in lower extremities by up to 62 mL/min. 2. Provides beneficial range of motion exercise for ankle joint.	1. Enhances blood flow in lower extremities. 2. Exercises ankle joint.
Sterility	The boot is not sterile and is disposable.	The wrap is not sterile and is not disposable.
Biocompatibility	The boot is the only element in contact with the user. It is constructed of biocompatible plastic which is prevented from direct contact with the user by a cotton leg covering	The foot paddles are the only elements in contact with the user. It is constructed of biocompatible plastic.

Parameter	Flo-Boot	PhleboPump
Mechanical safety	1. The inflatable bladder is sized such that it will not over-inflate and cause excessive dorsiflexion. 2. The control module has a fixed duration of pumping (1.5 sec) to prevent over - inflation and excessive dorsiflexion. 3. Upon interruption in power or in the event of any circuit failure in the control module, the device will default to the unpowered state, which has the bladder(s) open to atmosphere. In the event of a power failure the bladder(s) will deflate and the foot will return to the relaxed position. 4. Relevant contraindications will be prominently printed in the Flo-Boot manual and brochures. 5. Warnings will be prominently printed in the Flo-Boot manual and brochures, as well as being displayed on the control module itself. Also, a warning that the device is not explosion proof and should not be used in the presence of flammable anesthetics or gases will be included. 6. The devices manual and brochure will prominently note that this device is only to be used under physician's order.	1. The device has a fixed range of motion to prevent excessive dorsiflexion. 2. Relevant contraindications are printed in the product's instruction manual and brochure. 3. warnings are contained in the product's instruction manual and brochure. 4. The product's labeling indicates that the device is to be used only a physician's order.
Chemical safety	Uses no chemical elements	Uses no chemical elements
Anatomical sites	Foot and lower leg to mid-calf	Foot
Energy used and/or delivered	Pneumatic pump delivers air to inflatable element to maximum of 280 mmHg over a 1.5 sec cycle/time	Mechanically driven foot paddles.
Compatibility with environment and other devices	Should not be used in the presence of flammable or explosive gases or materials	Should not be used in the presence of flammable or explosive gases or materials
Where used	In controlled hospital setting and in non-hospital setting	In controlled hospital setting and in non-hospital setting.
Standards met	UL Standards for medical devices	UL Standards for medical devices
Electrical safety	Conforms to UL Standards for medical devices	Conforms to UL Standards for medical devices
Thermal safety	Generates no heat	Generates no heat

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 4 2001

Discovery Group, LLC
c/o Mr. Richard J. Freer, Ph.D.
Director, Business Development
8110 Westbury Drive
Richmond, VA 23229

Re: K003272
Trade Name: Flo-Boot Foot Dorsiflexion Device
Regulatory Class: II (Two)
Product Code: BXB
Dated: January 09, 2001
Received: January 10, 2001

Dear Dr. Freer:

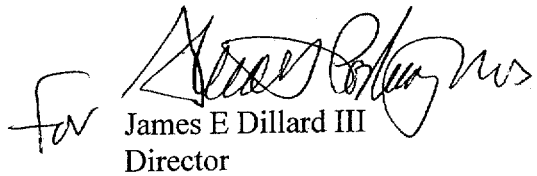
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



James E Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: K003272

Device Name: Flo-Boot™ Foot Dorsiflexion Device (Flo-Boot)

Indications for Use:

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Contraindications:

1. The device is contraindicated where pre-existing DVT is diagnosed or presumed.
2. The device is also contraindicated where pre-existing congestive heart failure is diagnosed or presumed.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

4-3-1

Division of Cardiovascular & Respiratory Devices
510(k) Number K003272